

### **REMARKS**

In view of the above amendments and following remarks, reconsideration of the objections and rejections contained in the Office Action of November 10, 2003 is respectfully requested.

First, it is noted that a number of minor editorial changes to generally improve the form of the application and to change the language to "U.S." English have been made.

A number of minor editorial changes have been made to the claims under consideration as well. In addition, claim 41 has been amended to include some limitations corresponding to those of independent claim 21. This will be discussed in detail below.

On page 2 of the Office Action, the Examiner noted that the Information Disclosure Statement submitted November 7, 2002 and March 10, 2003 were being considered by the Examiner. The Examiner further noted that some additional copies of references were present in the case. An additional IDS was in fact submitted by Applicant, and have not apparently been considered by the Examiner. For the Examiner's benefit, a copy of this Information Disclosure Statement, submitted April 22, 2002 is enclosed. Note that includes two forms PTO-1449. Copies of the references were previously submitted. However, should any of these references be missing, such can readily be forwarded by Applicant should the Examiner require them.

The Examiner rejected claims 21-40 as being indefinite for use of the phrase "Folk Ward". This position by the Examiner is respectfully traversed and submitted to be incorrect.

Folk Ward is a well-known statistical method for determining a weighted particle size in, for example, emulsions and suspensions. The method is generally accepted in the art of particle size determination. Accordingly, the use of the terms in the claims is a definite indication to one of ordinary skill in the art of the scope of the claims.

The Examiner's attention is directed to attachment B accompanying this Amendment. This document is a print-out from the Internet entitled "Sedimentology and stratigraphy of Minho River quaternary deposits." The print-out is an abstract which references the use of Fork-Ward statistics.

The Examiner's attention is further directed to attachment C, entitled "Quaternary Studies" from the Journal of the Portuguese Association for Quaternary Research. The English translation at the bottom of page 9 further indicates the use of the formulations of Folk-Ward (1957).

The Examiner's attention is further directed to attachment D, entitled "Characterization of Littoral Sands From Owen Beach in Tacoma, Washington State", also an Internet print-out. The abstract further discusses the use of Folk and Ward equations.

The Examiner's attention is further directed to attachment E, entitled "Sediment Size Analyses of the Owens Lake Core." This is another document which is a print-out from the Internet. In this document, on page 4 thereof, there is a further discussion of the Folk and Ward equations, setting forth such equations. Also note page 10, which references Folk and Ward (1957). Also note the Appendix on page 11.

Further note attachment F, entitled "Spatial Variability of Aeolian Sands On Starczynow 'Desert' (Eastern Part of Silesian Upland)." This is a further Internet print-out which indicates, in the second section on the first page, the use of the equations of Folk and Ward.

The Examiner contends that it is not clear whether the diameter taken by a different method would be equally operational. This consideration, however, is respectfully submitted to not be relevant to the consideration of whether the claims that reference the Folk Ward mean diameter being 25 to 100  $\mu\text{m}$  are definite in scope to one of ordinary skill in the art. In other words, whether or not the claim is definite is not influenced by whether or not there are other ways of claiming an "equally operational" method.

Accordingly, it is respectfully submitted that all of the evidence accompanying this response indicates that the Folk Ward method is one that is generally accepted in the art of particle size determination, is a definite limitation to one of ordinary skill in the art with respect to the scope of the claim and is not indefinite under 35 U.S.C. §112, second paragraph. Indication of such is respectfully requested.

On page 3 of the Office Action, the Examiner had rejected claims 21-24 and 26-41 as being unpatentable over Zimmerman, U.S. Patent 4,453,939 (Zimmerman). Further, on page 7, the

Examienr rejects claims 25 and 42-56 as being unpatentable over Zimmerman in view of Cioca et al., U.S. Patent 3,939,831 (Cioca) and Koken Co. However, it is respectfully submitted that the present invention, as set forth in the above-amended claims 21-56, clearly patentably distinguishes over each of Zimmerman, Cioca and Koken Co.

The present invention relates to a method of coating a carrier with a suspension comprising fibrinogen, thrombin and alcohol, as well as a method of drying such a coating of a carrier. Such a coated collagen carrier can be used as a ready-to-use absorbable composition for tissue glueing, tissue sealing and hemostasis.

One of the objective technical problems that are solved by the present invention is the problem of providing a suspension which confers low abrasion when it is applied as a dry coating to a carrier. Please note the discussion from line 43 of page 3 of the specification to line 2 of page 4. That is, it is an object of the invention to provide a coated collagen sponge with such a suspension which has a sufficient fixation of the coating to the collagen sponge, i.e. a satisfactory low abrasion of the coating when it is submitted to mechanical impact. Please also note page 9 of the specification, at lines 25-28, wherein it is discussed that low abrasion of the coating ensures that the coated collagen sponge may be transported, grabbed by a surgeon's hands and/or by a surgical instrument, and otherwise handled without loosening the dried suspension, i.e. the coating.

The present inventors have realized that fibrinogen and thrombin particles which have a Folk Ward mean diameter of 25-100  $\mu\text{m}$  in a fibrinogen-thrombin suspension confers low abrasion when the suspension is applied to a collagen carrier. Examples I-VII have various particle sizes throughout the claim range shown to result in satisfactory abrasion qualities. Example VIII contains a comparison between the suspension applied in accordance with the present invention and other commercially available products. As is apparent from the table on page 25, the present invention, the Collagen sponge Nycomed, is superior with respect to abrasion characteristics.

The invention is reflected in both independent claims 21 and 41. Claim 21 recites a method for coating a carrier with a suspension when the suspension contains fibrinogen and thrombin

particles, the Folk Ward mean diameter of the particles being 25-100  $\mu\text{m}$ . Claim 41 recites a method of drying a suspension as a coating on a surface of a carrier wherein the suspension contains fibrinogen and thrombin particles, the Folk Ward mean diameter of the particles being 25-100  $\mu\text{m}$ . Such is not disclosed or suggested by Zimmerman or the other references.

Zimmerman is directed to a composition for sealing and healing wounds. However, as the Examiner acknowledges, Zimmerman does not disclose or suggest the Folk Ward mean diameter of the particles of fibrinogen and thrombin being 25-100  $\mu\text{m}$ . Thus while one of ordinary skill in the art might recognize from Zimmerman that a coating including thrombin and fibrinogen may be used in a product for healing and sealing wounds, you would not find any indication in Zimmerman that certain particle sizes are beneficial with respect to abrasion characteristics. Zimmerman never mentions any specific particle size, and does not express any concern with the size of the particles.

For this reason alone, the Examiner's rejection fails to establish a *prima facie* case of obviousness of claims 21-24 and 26-41. As such, this rejection must be withdrawn.

The Examiner takes the position that the selection of an optimal particle size would have been evident to one of ordinary skill in the art. The Examiner reasons in hindsight that the particle size determines the relative surface area and thus reactivity, and that depending on how quickly the particles are required to react and the body to form a clot, an ordinary artisan would select an appropriate particle size. However, the Examiner's reasoning has no basis and any evidence of record. There is in fact no evidence cited by the Examiner that particle size determines the relative surface area and thus reactivity. There is no evidence of record cited to indicate that the person of ordinary skill in the art would select appropriate particle sizes depending on how quickly particles are required to react and the body to form a clot. Core factual findings in a patentability determination, however, must be supported by concrete evidence in the record. *In re Zurko*, 59USPQ 2d 1693. "With respect to core factual findings in a determination of patentability, however, the Board cannot simply reach conclusions based on its own understanding or experience-or on its assessment of what would be basic knowledge or commonsense. Rather, the Board must point to some concrete evidence in the record in support of these findings." *Id* at 1697.

The Examiner's attention is further directed to MPEP §2144.05, section II(B). While the Examiner states that the selection of an optimal particle size would have been evident to one of ordinary skill in the art, and that the determination of an optimum value of "cause effective variables" is within the skill of one practicing in the art, a particular parameter must first be recognized as a result-effective variable. That is, before the Examiner can say that the optimization of particle size would have been obvious, there must be a recognition in the prior art that the parameter of particle size is a variable which achieves a recognized result. *In re Antonie*, 195 USPQ 6 (CCPA 1977). In this case, Zimmerman does not recognize particle size as a result-effective variable. The reference to "fine particles" in one example of Zimmerman does not amount to a realization by Zimmerman that adjustment of the particle size to a particular range would be beneficial with respect to abrasion characteristics of the resulting product. Because Zimmerman does not recognize the particle size as such a result-effective variable, under *In re Antonie*, this may not be considered to be an obvious optimization. For this reason as well, the Examiner's rejection must be withdrawn.

A number of additional positions have been taken by the Examiner with respect to the applicability of Zimmerman to the claims being considered by the Examiner. Applicants reserve all rights to consider and traverse any such positions as is necessary at a later point in time. However, in view of the above clear distinction between Zimmerman and the present invention as reflected by claims 21 and 41, no further discussion at this point with respect to Zimmerman seems necessary.

The Examiner further cited Cioca and Koken Co. Similarly, in view of the above clear distinction between Zimmerman and the present invention reflected in claims 21 and 41, no further discussion of these references appears to be necessary at this time. Suffice to say that neither of these references cures the above deficiency of Zimmerman.

The various dependent claims provide additional distinctions over the references cited by the Examiner. Further discussion of these distinctions also does not appear necessary at this time, though Applicant reserves the right to argue any such further distinctions as necessary at a later point in time.

In view of the above it is respectfully submitted that all of the claims now pending in the present application clearly distinguish over Zimmerman, Cioca and Koken Co. Indication of such is respectfully requested.

In view of the above amendments and remarks, it is submitted that the present application is now in condition for allowance, and the Examiner is requested to pass the case to issue. If the Examiner should have any comments or suggestions to help speed the prosecution of this application, the Examiner is requested to contact Applicant's undersigned representative.

Respectfully submitted,

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